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EXAMINER				
LI QIAN JANICE				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
03/29/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/595,944

Applicant(s)

HAHN ET AL.

Examiner

Q. JANICE LI

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6, 7 and 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment and remarks filed 1/8/2010 are acknowledged. Claim 1 has been amended. Claims 1, 5 and 8-10 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. New ground of rejection is necessitated in view of the amendment. The arguments in 1/8/10 response would be addressed to the extent that they apply to current rejection.

Election/Restrictions

Applicant's election with traverse of Group I, drawn to claim 5 and linking claims 1-4, 8-10, is acknowledged. The applicant also elected a species defined by the combination of following elements: AP-1 as the candidate cis-acting regulatory element, luciferase as a specific reporter gene and immature dendritic cell as the host cell. Applicant indicated that element c) as listed in page 5 of the Restriction requirement is not deemed applicable. Hence, claims 1, 5, 8-10 read on the elected invention.

Claims 1-14 are pending, however, claims 2-4, 6, 7, 11-14 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1, 5 and 8-10 are under current examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chanda et al.* (USP 7,344,833), in view of *Riesbeck et al.* (Antimicrobial Agents Chemother 1998;42:1923-30) and *Kraal et al.* (J Exp Med 1986;163:981-97).

Chanda teaches methods for screening modulators of AP-1 transcription factor activities in a cell (e.g. the abstract). *Chanda* teaches AP-1 protein is normally expressed by lymphoid cells (immunocyte) and induces macrophage (immunocyte) phagocytosis and activation, and induces hematopoietic progenitor cell (immature dendritic cell) differentiation (e.g. column 1, lines 41-50). *Chanda* teaches when using cell-based assays, the steps for the screening include introducing into appropriate host cells vectors expressing a reporter gene and linked to the coding sequence of an AP-1 subunit under the control of an AP-1 transcription regulatory element (promoter and enhancer sequence); and activities of modulation are typically examined by measuring expression of the reporter genes (column 25, lines 41-59). In working examples, *Chanda* transfected HEK293 cells with a vector construct comprising a nucleic acid encoding AP-1 operably linked to luciferase reporter gene, applying a candidate modulator (stimulator) of AP-1, and measuring reporter gene activity in response to the modulator (e.g. figure 2). *Chanda* teaches the vector for delivering the nucleic acid may be adenoviral vectors (column 34, lines 3-14). Although *Chanda* did not transfect an

immunocyte in working examples, it was apparently known in the art that immunocytes are natural host cells for AP-1 as taught by *Chanda*.

Riesbeck supplemented *Chanda* by establishing the skilled in the art had reduced to transfect primary immunocyte with a plasmid comprising a reporter gene chloramphenicol acetyltransferase (CAT). *Riesbeck* teaches transfecting isolated human peripheral blood lymphocytes with a reporter plasmid containing IL-2-CAT reporter gene operably linked to a promoter (see e.g. figure 2), co-incubating the transfected primary lymphocytes with Ciproflaxin, comparing several gene activities between cells incubated or not-incubated with Cipro, and measuring reporter gene activity to assess the effect of cipro. *Riesbeck* reports AP-1 activity was increased in stimulated purified Th lymphocytes incubated with ciproflaxin (e.g. the abstract and figures 2-3).

Chanda in view of *Riesbeck* does not particularly teach immature dendritic cells. However, it was well known in the art that veil cells are immature dendritic cells. *Kraal* supplemented *Chanda* in view of *Kikuchi* by establishing methods of identifying iDC were well known in the art (e.g. the abstract and table I).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine whether a stimulus is capable of activating a AP-1 cis-acting regulatory element in a primary immunocyte according to the knowledge as illustrated in *Chanda* in view of *Riesbeck* and *Kraal* to arrive at the claimed process and with a reasonable expectation of success. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Response to Arguments

In the remarks, the applicant argues that although Kikuchi mentioned primary immunocytes, Kikuchi transfected THP-1 cells, (which is a monocytic leukemia cell line), not primary immunocyte. Applicant also amended claims to specifically require "primary immunocyte".

To address the limitation, a new ground of rejection has been applied to the claims, wherein *Riesbeck* established that the skilled in the art had reduced to practice transfecting primary immunocytes. Accordingly, it would have been obvious to the skilled in the art to determine whether to use primary immunocytes or immune cell lines as host cells depending on the goal of study.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9 AM -7:00pm, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

*/Q. JANICE LI/
Primary Examiner, Art Unit 1633*